

Editorial

HIV/AIDS Prevention: The Key to Turn the Tide Needs Galvanized Innovations

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The largest HIV/AIDS conference in history was convened in Toronto in August, 2006. Following the United Nations Summit in June where world leaders proclaimed an “unprecedented human catastrophe,” the epidemic continues to grow with new cases outpacing treatment. Currently, 40 million HIV positive people live while over 5 million annually (14,000/day) are infected with HIV. Condoms and counseling have not been enough – the virus spreads to 5 million more people worldwide each year.

Nonetheless, over 20,000 AIDS researchers, campaigners, patients joined governments, NGOs and the private sector to further explore mechanisms to address this major health threat in countries around the world that has already killed 25 million people. The theme for the 16th conference on HIV is “Time to Deliver.” Recalling the “successful” AIDS conference in Canada in 1996, when HAART was introduced to revolutionize AIDS treatment, this year’s conference is looking for fresh hope with new means of prevention, expansion of treatment as an outright cure or vaccine is not in sight. The “promised” vaccine still may be a decade away from delivery. To stem the tide of the epidemic, the only means to combat the disease, is to advance prevention.

In 2004, the Global HIV Prevention Working Group, a panel of nearly 50 international experts in HIV prevention, stressed a major shift in HIV prevention as a means to avoid a rise in HIV transmission and acceleration of the epidemic. Yet, the political reality for addressing prevention has been limited. Unless the incidence of HIV infection is sharply reduced, treatment will not be able to keep pace with all those who will need therapy. Hence, experts warn that integration of prevention and treatment strategies must take place. The Group called for annual funding for HIV prevention and care to increase from \$4.7 billion in 2003 to \$10.5 billion in 2005 and \$15 billion in 2007, as recommended by UNAIDS.

It is time to address the prevention programs shortfall (e.g., ABC) and enhance programs that principally address knowledge, personal risk perception and self-efficacy, behavior change, gender inequalities and social norms. An additional investment should be made; scientific innovation and intervention has untapped promise for prevention. The greatest success in treating HIV has been the medical progress in developing effective ARVs for those infected. Vaccine research has been challenged, despite the financial investment and continued announcements of “within a decade.” Microbicides are showing promise, but will present challenges for large scale prevention.

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Early scientific evidence suggests that the idea of pre-exposure prophylaxis—a quasi-vaccine to prevent HIV infection—has great promise for addressing the growing incidence. One of the initial successes presented in Toronto was such an idea where an antiretroviral medicine was given to HIV negative women to prevent disease. While the result were preliminary with limited participants due to the ethical challenges, Dr. Helene Gayle, president of the antipoverty group CARE and co-chair of the International AIDS Conference in Toronto, suggested such an approach is “incredibly encouraging,” as a drug “would be an incredibly important new prevention tool that we should make available as soon as possible.” Bill and Melinda Gates both called and offered financial incentives to help develop or an oral prevention drug for HIV.

In the absence of a safe and effective HIV vaccine or universally used microbicide or barrier device, such pre-exposure prophylaxis measures such oral drugs or injectables warrant exploration. A scientific rationale exists to consider use of current therapeutic antiretrovirals as agents to prevent or lessen the risk of primary infection. Much of the current supportive evidence comes from post-exposure prophylaxis data. The approach of using combination antiretroviral therapy following a high risk exposure to an HIV-infected individual, post-exposure prophylaxis is well accepted. This approach is supported by both animal and human studies. Additionally, the use of current antiretrovirals has been successful in decreasing the risk of mother to child transmission of HIV and is now considered standard of care.

The accumulated data suggests that current antiretroviral agents can decrease HIV transmission and should be explored for pre-exposure prophylaxis in individuals at high risk for infection or those that would not use other prevention methods. Of course, this strategy requires that the drugs used for this purpose are safe and effective, which would need to be demonstrated in clinical trials. The benefit/risk balance for this approach also must be favorable, both on an individual and population level for this to be an acceptable strategy. Antiretrovirals which have a long elimination half life, and which are safe and convenient would be best suited for this application. Additionally, other drugs from classes which are under development, such as various entry inhibitors, may also be good candidates based on their mechanism of action; however, this remains to be proven to date.

Ideally, ethical challenges of conducting such trials with hopeful prospects will be advanced by donors and related organizations that can help extrapolate beneficence from a cohort to the millions infected annually. A new initiative should begin to challenge the biomedical community to explore and develop an ARV formulation to prevent HIV infection. The ultimate goal of this challenge would be for the private sector to develop and test a formulation (e.g. ARVs in oral or long acting form) that would provide protection from HIV infection. Ideally, with the appropriate coalition this would be expedited and supported for developing a non-profit partnership that would foster, facilitate and support clinical trials in resource poor settings where HIV continues unabated. It would be realistic to envision that development and clinical trials could be conducted concurrently while the business framework for bringing this to scale is finalized. The goal would be that in subsequent HIV conferences, this pre-exposure prevention/prophylaxis would become a new weapon against HIV. Additionally, through the design it should foster implementing capacity for HIV prevention and treatment with devolution to developing country institutions who would engage in the research and distribution.